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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,594	06/11/2007	Yusuke Nakamura	082368-008900US	8459

20350 7590 09/04/2008

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EXAMINER	
REDDIG, PETER J	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
09/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,594	NAKAMURA ET AL.	
	Examiner	Art Unit	
	PETER J. REDDIG	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-8, drawn to a method of diagnosing CRC or a predisposition to developing CRC in a subject, comprising determining a level of expression of C10orf3 in a patient derived biological sample, wherein an increase of said level compared to a normal control level of said gene indicates that said subject suffers from or is at risk of developing CRC.

Claims 29 links inventions 2 and 3. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 29. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP ' 804.01.

Group 2, claim(s) 9 and 12-14, drawn to a method of screening for a compound for treating or preventing CRC, said method comprising the steps of: a) contacting a test compound with a

polypeptide encoded by a nucleic acid of C10orf3; b) detecting the binding activity between the polypeptide and the test compound; and c) selecting a compound that binds to the polypeptide and a composition comprising said compound and a pharmaceutically acceptable carrier.

Group 3 claim(s) 10, 11, and 15, drawn to a method of screening for a compound for treating or preventing CRC, said method comprising the steps of: a) contacting a candidate compound with a cell expressing C10orf3, and b) selecting a compound that reduces the expression level of C10orf3 and a composition comprising said compound and a pharmaceutically acceptable carrier.

Group 4, claim(s) 17-21, drawn to a method of treating or preventing CRC in a subject comprising administering to said subject an antisense composition, said composition comprising a nucleotide sequence complementary to a coding sequence of C10orf3.

Group 5, claim(s) 22, drawn to a method for treating or preventing CRC in a subject comprising the step of administering to said subject a pharmaceutically effective amount of an antibody or fragment thereof that binds to a protein encoded by nucleic acid of C10orf3.

Group 6, claim(s) 23, drawn to a method of treating or preventing CRC in a subject comprising administering to said subject a vaccine comprising a polypeptide encoded by a nucleic acid of C10orf3 or an immunologically active fragment of said polypeptide, or a polynucleotide encoding the polypeptide.

Group 7, claim(s) 24, drawn to a method for treating or preventing CRC in a subject, said method comprising the step of administering a compound that is obtained by the method according to any one of claims 9-15.

Claims 16 links inventions 8 and 9. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 16. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory

double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP ' 804.01.

Group 8, claim(s) 25-27 and 30-36, drawn to a composition for treating or preventing CRC, said composition comprising a pharmaceutically effective amount of an antisense polynucleotide or small interfering RNA against a polynucleotide of C10orf3 as an active ingredient, and a pharmaceutically acceptable carrier and a kit comprising a detection reagent which binds to nucleic acid sequence of C10orf3

Group 9, claim(s) 28, drawn to a composition for treating or preventing CRC, said composition comprising a pharmaceutically effective amount of an antibody or fragment thereof that binds to a protein encoded by nucleic acid of C10orf3 as an active ingredient, and a pharmaceutically acceptable carrier and a kit comprising a detection reagent which binds polypeptide of C10orf3.

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features which define a contribution over the prior art. If there is no special technical feature, if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d).

The inventions listed as Groups 1-9 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups 1-9 appears to be the C10orf3 gene. However, WO 2002/083068 (Challita-Eid, P.M., et al. 24 October 2002) teaches the C10orf3 protein and

nucleic acid sequence and antibodies to the protein, which is named 121P2A3, see figure 1 and 2A and the claims. WO 2002/083068 also teaches detecting increased expression C10orf3/121P2A3 in colon cancer compared to control levels, see Example 4 and Figure 14. Therefore, the technical feature linking the inventions of Groups 1-9 does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Species Elections for Group 6

A. Claim 23 is generic to the following disclosed patentably distinct species of vaccine:

1) a vaccine comprising a polypeptide encoded by a nucleic acid of C10orf3 or an immunologically active fragment of said polypeptide

2) a vaccine comprising a polynucleotide encoding the polypeptide

Species Elections for Group 7

A. Claim 24 is generic to the following disclosed patentably distinct species of compounds:

1) a compound that is obtained by the method according to any one of claims 9 and 12-14

2) a compound that is obtained by the method according to any one of claims 10, 11, and 15

The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to

petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached at (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Peter J Reddig/
Examiner, Art Unit 1642

/P. J. R./

Appendix 1

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ABP83629
ID   ABP83629 standard; protein; 464 AA.
XX
AC   ABP83629;
XX
DT   15-JUN-2007  (revised)
DT   28-MAR-2003  (first entry)
XX
DE   Human 121P2A3 v.9.
XX
KW   Human; 121P2A3; cytostatic; immunostimulant; vaccine;
KW   humoral immune response; cellular immune response; BOND_PC;
KW   up-regulated in colon cancer 6;
KW   up-regulated in colon cancer 6 [Homo sapiens]; GO7049; GO7067; GO51301.
XX
OS   Homo sapiens.
XX
PN   WO200283068-A2.
XX
PD   24-OCT-2002.
XX
PF   09-APR-2002; 2002WO-US011359.
XX
PR   10-APR-2001; 2001US-0282739P.
PR   25-APR-2001; 2001US-0286630P.
PR   22-JUN-2001; 2001US-0300373P.
XX
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PA   (AGEN-) AGENSYS INC.
XX
PI   Challita-Eid PM,  Raitano AB,  Faris M,  Hubert RS,  Mitchell SC;
PI   Afar DEH,  Saffran D,  Morrison K,  Morrison RK,  Ge W,  Jakobovits A;
XX
DR   WPI; 2003-092956/08.
DR   N-PSDB; ABV99868.
DR   PC:NCBI; gi76093187.
DR   PC:SWISSPROT; Q53EZ4.
XX
PT   New composition comprising a substance that modulates the status of
PT   121P2A3 polypeptides, useful for eliciting humoral or cellular immune
PT   responses or in assessing the status of 121P2A3 gene products in normal
PT   versus cancerous tissues.
XX
PS   Claim 1; Fig 2I; 362pp; English.
XX
CC   The invention relates to a novel composition comprising a substance that
CC   modulates the status of a protein, 121P2A3. The composition of the
CC   invention has cytostatic and immunostimulant activity, and is useful as a
CC   vaccine. The 121P2A3 proteins and polynucleotides are useful for
CC   eliciting humoral or cellular immune response. The polynucleotides are
CC   useful for characterising cytogenetic abnormalities of this chromosomal
CC   locus, as tools that can be used to delineate cytogenetic abnormalities
CC   in the chromosomal region that encodes 121P2A3 that may contribute to
CC   malignant phenotype, and in assessing the status of 121P2A3 gene products
CC   in normal versus cancerous tissues. The proteins are useful for
CC   generating and characterising domain-specific antibodies, for identifying
CC   agents or cellular factors that bind to 121P2A3 or a particular structure
CC   domain, and in various therapeutic and diagnostic contexts, including
CC   cancer vaccines. The antibodies or T cells reactive with the product are
CC   useful in passive or active immunisation, and in imaging methodologies
CC   for the management of cancer. The present sequence represents the 121P2A3
CC   v.9 protein product
CC
CC   Revised record issued on 15-JUN-2007 : Enhanced with precomputed
CC   information from BOND.
XX
SQ   Sequence 464 AA;

  Query Match           100.0%;  Score 2330;  DB 6;  Length 464;
  Best Local Similarity   100.0%;  Pred. No. 5.7e-153;
  Matches  464;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 MSSRSTKDLIKSKWGSKPSNSKSETTLEKLKGEIAHLKTSVDEITSGKGKLTDKERHRLL 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MSSRSTKDLIKSKWGSKPSNSKSETTLEKLKGEIAHLKTSVDEITSGKGKLTDKERHRLL 60

Qy         61 EKIRVLEAEKEKNAYQLTEKDKEIQRLRDQLKARYSTTALLEQLEETTREGERREQVLKA 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 EKIRVLEAEKEKNAYQLTEKDKEIQRLRDQLKARYSTTALLEQLEETTREGERREQVLKA 120

Qy        121 LSEEKDVLKQQLSAATSRIAELESKTNTLRLSQTVAPNCFNSSIINNIHEMEIQLKDALEK 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 LSEEKDVLKQQLSAATSRIAELESKTNTLRLSQTVAPNCFNSSIINNIHEMEIQLKDALEK 180

Qy        181 NQQWLVYDQQREVYVKGLLAKIFELEKKTETAAHSLPQQTKKPESEGYLQEEKQKCYNDL 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 NQQWLVYDQQREVYVKGLLAKIFELEKKTETAAHSLPQQTKKPESEGYLQEEKQKCYNDL 240
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Qy        241 LASAKKDLEVERQTITQLSFELSEFRRKYEETQKEVHNLNQLLYSQRRADVQHLEDDRHK 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 LASAKKDLEVERQTITQLSFELSEFRRKYEETQKEVHNLNQLLYSQRRADVQHLEDDRHK 300

Qy        301 TEKIQKLREENDIARGKLEEEKKRSEELLSQVQFLYTSLLKQQEEQTRVALLEQQMQACT 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 TEKIQKLREENDIARGKLEEEKKRSEELLSQVQFLYTSLLKQQEEQTRVALLEQQMQACT 360

Qy        361 LDFENEKLDRQHVQHQLHVILKELRKARNQITQLESLKQLHEFAITEPLVTFQGETENRE 420
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        361 LDFENEKLDRQHVQHQLHVILKELRKARNQITQLESLKQLHEFAITEPLVTFQGETENRE 420

Qy        421 KVAASPKSPTAALNESLVECPKCNIQYPATEHRDLLVHVEYCSK 464
              |||||||||||||||||||||||||||||||||||||||||||||
Db        421 KVAASPKSPTAALNESLVECPKCNIQYPATEHRDLLVHVEYCSK 464
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